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Gregory Turocy
Amin & Turocy, LLP
24th Floor, National City Center
1900 East 9th Street
Cleveland, OH 44114

EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TOYOKO KUSAMA, KOICHI KADOWAKI,
and TETSUYA NOMURA

Appellants

Appeal 2009-001929
Application 10/826,119
Technology Center 1600

Decided[1]: June 9, 2009

Before RICHARD TORCZON, SALLY GARDNER LANE and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

LANE, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

I. STATEMENT OF THE CASE

The appeal, under 35 U.S.C. § 134, is from a Final Rejection of claims 24, 25 and 35. Claims 1-23, 26-34, 36 and 37 have been withdrawn as being drawn to non-elected subject matter. (App. Br. 2). We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Appellants claim a primer pair and a kit comprising a primer pair for the detection of a ruminant-specific DNA.

The Examiner relied on the following documents:

Saulle et al., *Rapid Communication: Nucleotide Sequence of Chamois, Alpine Ibex, and Red Deer tRNA^{Lys} and ATPase8 Mitochondrial Genes*, 77 J. Animal Sci. 3398-99 (1999); and

Lowe et al., *A Computer Program for Selection of Oligonucleotide Primers for Polymerase Chain Reactions*, 18 Nucleic Acids Res. 1757-61 (1990).

The Examiner rejected claims 24, 25 and 35 under 35 U.S.C. § 103(a) over Saulle and Lowe. We focus on claim 24 as a representative claim. *See* 37 C.F.R. § 41.37(c)(1)(vii).

II. LEGAL PRINCIPLES

"If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007).

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the

product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR*, 550 U.S. at 421.

III. ISSUE

Would those of skill in the art have had a reason to select the ruminant-specific DNA primers within the DNA sequence reported in Saulle?

IV. FINDINGS OF FACT

1. Appellants' claim 24 recites[2]:

> A primer pair for detection of a ruminant-specific DNA, the primer pair being
> a combination of the DNA sequence of SEQ ID NO: 3 and the DNA sequence of SEQ ID NO: 4, or
> a combination of the DNA sequence of SEQ ID NO: 5 and the DNA sequence of SEQ ID NO: 6.

(App. Br. 15, Claims App'x).

2. Appellants' specification reports the results of PCR analysis with primers of SEQ ID NO: 5 and SEQ ID NO: 6, demonstrating that

> PCR products from DNAs derived from cattle, sheep, goat, and deer which are ruminants, were more clearly observed (104 bp band position). On the other hand, PCR products (DNA fragments) could not be detected in the DNA samples of animals that were not ruminants. . . . [T]he combination of Fpr-F [SEQ ID NO: 5] and Fpr-R [SEQ ID NO: 6] is a primer pair that specifically detects DNAs derived from animal species of ruminant origin.

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[2] Claim 24 has been reformatted to add indentations. *See* 37 C.F.R. § 1.75(i).

(Spec. 17-18).

3. Saulle teaches:

> The considerable nucleotide variation of the *tRNA*^{Lys} and *ATPase8* genes among species belonging to the *Pecora* infraorder[3] makes the *tRNA*^{Lys}*-ATPase8* coding region a very informative target sequence in PCR-based assays for species identification of meat and meat-derived products. By using an appropriately designed species-specific primer pair within the *tRNA*^{Lys}*-ATPase8-ATPase6* sequence, we developed a PCR-based procedure for rapid detection and identification of bovine mitochondrial DNA from animal feeds and complex food matrices . . . .

(Saulle 3398, right col.).

4. Saulle teaches a genetic sequence, the *tRNA*^{Lys}*-ATPase8* of alpine ibex, which contains within it the sequence of SEQ ID NO: 5 and SEQ ID NO: 6 recited in Appellants' claim 24. (Saulle 3399, left col.; SCORE Search Results).

5. Saulle does not teach where the specific sequences of SEQ ID NOS: 5, or 6 begin or end.

6. Those of skill in the art would have known how to obtain primers from a genetic sequence using the algorithms taught in Lowe or other similar algorithms.

V. ANALYSIS

Appellants' claim 24 recites primer pairs with specific DNA sequences. The primer pairs are used "for detection of a ruminant-specific DNA . . . ." (FF 1). "A mere statement of a new use for an otherwise old or

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[3] We understand the "*Pecora* infraorder" to include most ruminants.

obvious composition cannot render a claim to the composition patentable." *In re Zierden*, 411 F.2d 1325, 1328 (CCPA 1969). Thus, if it would have been obvious for those of skill in the art to determine the sequence of the claimed primer pairs, Appellants' claims are not patentable under 35 U.S.C. § 103(a).

Saulle teaches that the *ATPase8* gene sequence is informative for species identification in meat products, specifically detection of bovine DNA. (FF 3). Saulle teaches a DNA sequence, from alpine ibex, which includes within it the sequence of SEQ ID NOs: 5 and 6 (FF 4), but does not identify where the sequences of SEQ ID NOs: 5 or 6 begin or end. (FF 5). Lowe indicates that those of skill in the art knew how to derive operable primers from larger DNA sequences. (FF 6).

Those of skill in the art would have had reason to identify and isolate ruminant-specific primers in the alpine ibex *APTase8* gene sequence because Saulle teaches that these primers are useful for detection of bovine DNA. Lowe teaches that those skilled in the art would have been able to identify and isolate primers with the alpine ibex *ATPase8* gene sequence. Thus, it would have been obvious to use the method of Lowe to produce substitute primers for detection of ruminant-specific DNA. *See KSR,* 550 U.S. at 417, 421.

Appellants agree that "Saulle et al discloses the complete nucleic acid sequence to be detected," (App. Br. 5), but argue that

> [a]s long as the target sequence to be amplified cannot be selected appropriately, even if the known nucleic acid sequence of Saulle et al is combined with the step of generating and designing primers as taught by Lowe et al, the specific combination of primers of the claimed invention could not be

> obtained by those skilled in the art. In other words, one skilled in the art would not have expected to obtain primers capable of discriminating between homologous sequences without extensive experimentation to determine which primers actually perform as desired in PCR. This is because Saulle et al does NOT teach or suggest whether or not the ruminant DNA can be actually detected without detecting DNAs other than the ruminant DNA.

(App. Br. 5). We disagree with Appellants that Saulle does not teach detection of ruminant DNA because it expressly states that the *ATPase8* gene is "a very informative target sequence in PCR-based assays for species identification of meat and meat-derived products." (FF 3). Furthermore, Saulle teaches that primer pairs have been developed from that gene for detecting bovine DNA. (*Id.*). The Examiner found, relying upon Lowe, that one skilled in the art would have been able to identify and isolate primers within the sequence taught by Saulle. We accept this finding since the record indicates that those of skill in the art would have been able to conduct PCR experiments, such as those referred to in Saulle, to determine if a primer pair could differentiate ruminant species. (*See* FF 2). Appellants have argued, but not directed us to evidence showing, that it would have required "extensive experimentation" to determine other primer pairs from the alpine ibex *ATPase8* gene, including those claimed. Appellants have not shown that the identification of the primers would have been unexpected. Unexpected results must be established with factual evidence, not attorney arguments or conclusory statements. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

Appellants also argue that "while one skilled in the art might conceivably expect Saulle et al to be useful in generating primers capable of

amplifying an ATPase8 target, none of the optimization steps of Lowe et al indicates that such primers can discriminate between two homologous ATPase8 targets." (App. Br. 6). The Examiner did not rely upon Lowe as teaching the ability of primers from the *ATPase8* sequence to discriminate between homologous targets. This is taught by Saulle. Thus, we are not persuaded that because Lowe lacks specific steps to compare sequences or determine discriminatory primers, the claimed primer pairs would not have been obvious.

Appellants argue that

> a close reading of Lowe et al suggests that the program will not produce the claimed primers. On page 1758, column 1, first paragraph of Lowe et al, Lowe et al teaches that "[a]ll primers should contain a GC-type sequence pair (i.e., either a CC, GG, GC, or CG) at their 3' end." . . . None of the claimed primer sequences have a GC-type sequence pair at their 3' end. Therefore, the program of Lowe et al will not produce any of the claim[ed] primers regardless of any sequence entered into the program.

(Reply Br. 4). Lowe supports the Examiner's finding that at the time of Appellants invention those ordinarily skilled in the art would have been able to determine primer sequences from a larger genetic sequence. While some of the specific rules of Lowe might not apply in identifying and isolating the primers within the Saulle sequence, Appellants have not argued, nor directed us to evidence showing, that one skilled in the art would have been unable to identify primers within a larger sequence.

Finally, Appellants argue that "[t]hose having ordinary skill in the art are normally motivated to select primers that flank the coding region for a gene, since under such conditions the entire gene i[s] amplified by PCR for

purposes of sequencing, cloning, or sub-cloning" (Reply Br. 5-6), but that the claimed primer pairs are found "well within the coding region of the . . . gene . . . ." (Reply Br. 6). While Appellants' argument demonstrates that those of skill in the art were capable of deriving primer sequences, Appellants have not supported this specific argument with evidence that those of skill in the art would *not* have looked to sequences within the coding region to derive the claimed primers. "Argument of counsel cannot take the place of evidence lacking in the record." *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA 1977). Accordingly, we are not persuaded by Appellants' argument.

VI. CONCLUSIONS OF LAW

Those of skill in the art have had a reason to search for ruminant-specific DNA primers in the DNA sequence reported in Saulle.

VII. ORDER

Upon consideration of the record and for the reasons given, the rejection of claims 24, 25, and 35 under 35 U.S.C. § 103(a) over Saulle and Lowe is AFFIRMED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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cc:

Gregory Turocy
Amin & Turocy, LLP
24th Floor, National City Center
1900 East 9th Street
Cleveland OH 44114